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09/358,116

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/358,116	07/21/99	BACKSTEIN	R 0152.00004

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EXAMINER	
GAMBLE, P	
ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 11/06/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 10/24/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-29 is/are pending in the application.

Of the above, claim(s) 5-29 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

DETAILED ACTION

1. Applicant's election with traverse of Invention I (claims 1-4) in Paper No. 4 is acknowledged.

Applicant asserts that all of the claims relate to the glycoprotein and antibodies thereof and, in turn, relate to the L-selectin glycoprotein or methods of using the same. Applicant submits that examination of all of the claims in a single application would be efficient, thereby promoting the grounds for establishment of the restriction requirement practice.

Applicant's arguments are not found persuasive for the reasons of record set forth in the Restriction Requirement, mailed 8/22/00 (Paper No. 3), whereby the products and methods were indicated to be patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-29 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-4 are being considered in the instant application.

2. Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification broadly describes and the claims recite as part of the invention the following:

"An isolated and purified glycoprotein and functional analogues thereof characterized by being expressed on at least primitive hematopoietic cells; being a ligand for L-selectin; the binding of the ligand to L-selectin not being inhibited by anti-CD34 antibody; being resistant to O-sialogylcoprotein endopeptiddase activity; not being recognized by MECA-79 a monoclonal antibody which identifies ligands of L-selectin on lymph node high endothelial venules; and being sulfation-independent"
"And functional analogues thereof".

Such "glycoprotein" and "functional ligands" do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

Applicant relies upon identifying KG1a L-selectin ligand which binding activity is not sulfate-dependent utilizing an adherence assays; however applicant has not provide sufficient structural information that identifies a physiologic structure.

In addition, as indicated in Sackstein et al., Blood 89: 2773-2781, 1997; applicant's own work acknowledges efforts are directed at isolating and characterizing the structure of the claimed KG1a L-selectin ligand (see entire document, including the Discussion). Here, it is noted that the structural features of the claimed KG1a L-selectin ligand remain to be determined

Also, Sackstein et al. Notes that the structural determinants conferring L-selectin binding may vary in a cell and tissue-specific manner (see Abstract and Discussion). ; yet applicant has not provided such structural information.

Further, there is a lack of written description for "functional analogs"; given the absence of structural features that define the claimed "KG1a L-selectin ligand".

The specification as filed does not provide sufficient written description support for the claimed "KG1a L-selectin ligand" and "functional analogs thereof".

The skilled artisan cannot envision the claimed "L-selectin ligand" and "functional analogs thereof" in the absence of a detailed chemical structure of the "L-selectin ligand" and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Here, defining structural features are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

8. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

Applicant has not provided sufficient biochemical information (e.g. amino acid sequence) that distinctly identifies the claimed "KG1a L-selectin ligand" and "functional analogs thereof". While "L-selectin ligand" may have some notion of the activity of the claimed glycoprotein and applicant has relied upon the property of being sulfation-independent as well as the combination of characteristics to distinguish the instant glycoprotein from other L-selectin ligands; claiming biochemical molecules by certain functional attributes fails to enable the skilled artisan to make and use the claimed glycoprotein, without defining what the disclosed and claimed "KG1a L-selectin ligand" is made up of. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

However, the precise structural features that direct binding activity for the claimed nonconventional L-selectin ligand remains to be determined The isolation and characterization of the structure of this molecule has not been set forth, therefore the scope of the claimed isolated and purified glycoproteins functional analogs characterized by properties (a)-(e) cannot be ascertained. Again, the claimed and disclosed characteristics may have some notion of the activity of the glycoprotein as an adhesion molecule, there is insufficient precision in the claims which distinctly claims the isolated and purified glycoprotein and functional analogs thereof.

In addition, as indicated in Sackstein et al., Blood 89: 2773-2781, 1997; applicant's own work acknowledges efforts are directed at isolating and characterizing the structure of the claimed KG1a L-selectin ligand (see entire document, including the Discussion). Here, it is noted that the structural features of the claimed KG1a L-selectin ligand remain to be determined after applicant's priority dates. Here, the post-filing date reference relies upon the same or nearly the same functional characterization as that disclosed in the specification as filed and acknowledges that the KG1a L-selectin ligand has not been isolated and characterized to the point that the skilled artisan could make and use the claimed "L-selectin glycoprotein" and " functional analogs thereof" as an L-selectin ligand on primitive hemopoietic stem cells.

Here, Sackstein et al. acknowledges the existence and structural as well as functional attributes of known L-selectin ligands in distinguishing the claimed/disclosed "KG1a L-selectin ligand" (see Introduction and Discussion).

Also, Sackstein et al. Notes that the structural determinants conferring L-selectin binding may vary in a cell and tissue-specific manner (see Abstract and Discussion). ; yet applicant has not provided such structural information.

Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality (e.g. L-selectin ligand) requires a knowledge of and guidance with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which a polypeptide's structure relates to its functional usefulness. However, the problem of predicting polypeptide structure from mere sequence data of a single amino acid sequence and in turn utilizing predicted structural determinations to ascertain binding or functional aspects KG1a L-selectin analogs and finally what changes can be tolerated with respect thereto is complex and well outside the realm of routine experimentation. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. As pointed out herein, the specification as filed as well as a post-filing date reference has not provided sufficient structural or biochemical information to enable the skilled artisan to make and use the claimed KG1a L-selectin ligand. Further, I has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. Because of the lack of sufficient guidance and predictability in determining which modifications would lead to "functional analogs" of the claimed/disclosed "KG1a L-selectin ligand" and "analogs thereof" and that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at enabling the "KG1a L-selectin ligand and "functional analogs".

Without sufficient guidance, making and using the claimed "KG1a L-selectin ligand" and "functional analogs" thereof, including cell-l and tissue-specific L-selectin ligands is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

9. Claims 1-4: It is apparent that the MECA-79 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

10. Claims 1-4: Upon consideration of the specification,; it appears that the "KG1a" cell line is required to practice the claimed invention. It appears that applicant has relied upon characterizing the "claimed KG1a L-selectin ligand" by functional screening of the KG1a cell line (see the instant specification). As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line. See 37 CFR 1.801-1.809.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 1-4 are rejected under 35 U.S.C. § 102(a) as being anticipated by Sackstein et al. (Exptl. Hematol. 22: 788, 1994; Abstract 414). Sackstein et al. teach the indication of a KG1a L-selectin ligand that appears to be the same L-selectin ligand claimed (see Abstract). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced KG1a L-selectin ligand.

14. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
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Technology Center 1600
November 6, 2000